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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,289	08/21/2006	Debbie Stevens-Wright	B1075.71018US01	1531

23628 7590 12/31/2008
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EXAMINER

SCOTT, AMANDA L

ART UNIT	PAPER NUMBER
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4185

MAIL DATE	DELIVERY MODE
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12/31/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/551,289	Applicant(s) STEVENS-WRIGHT, DEBBIE	
	Examiner AMANDA SCOTT	Art Unit 4185	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/14/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 35 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following phrase is ambiguous as to what “portion”

Applicant is referring to:

and the second diameter portion having a length that is larger than a largest diameter of the second diameter portion; and attaching the electrode to the shaft, wherein the transition face and the sheath form sidewalls of a channel and the first diameter portion of the electrode forms a base of the channel.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claims 1-3, 5-14, 16, 18-21, 23-24, 26-34** are rejected under 35 U.S.C. 102(b) as being anticipated by Cunningham et al. (US 4,896,671).

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Regarding claim 1, Cunningham et al, discloses a catheter shaft having an insulating material and a diameter((54); column 3, lines 15-19; column 4, lines 67-68;); and an ablation electrode(20) forming a junction with the shaft (view fig 2 and 3), the ablation electrode having an exposed surface (view figure 3 (20)); wherein, extending from the junction, the exposed electrode surface has a first diameter portion with a first diameter that is smaller than the shaft diameter, the first diameter portion forming an angle with the insulating material; and wherein the exposed electrode surface has a second diameter portion with a second diameter that is larger than the first diameter of the first diameter portion, the second diameter portion having a largest diameter that is smaller than a length of the second diameter portion(column 4, line 67- column 5, line 19).

Regarding claim 2, Cunningham et al discloses the exposed electrode surface further comprises a transition face extending from the first diameter portion to the second diameter portion, the transition face forming an approximately 90 degree angle with the first diameter portion (view figure 2).

Regarding claim 3, Cunningham et al. discloses the insulating material(54), the first diameter portion and the transition face form a recessed region that allows blood to flow across the first diameter portion and the transition face when the electrode(20) is placed in a blood flow(view figures 2 and 3).

Regarding claim 5, Cunningham et al. discloses the ablation electrode is a distal tip ablation electrode (column 9, lines 25-29).

Regarding claim 6, Cunningham et al. discloses the ablation electrode is a ring ablation electrode (column 7, lines 11-15).

Regarding claim 7, Cunningham et al. discloses wherein the transition face forms an approximately 90 degree angle with the exposed surface of the second diameter portion (view figure 2 and 3).

Regarding claim 8, Cunningham et al. discloses wherein the distance from the insulating material to the transition face along the first diameter portion is larger than 0.3 millimeters (column 6, lines 49-61).

Regarding claim 9, Cunningham et al. discloses wherein the distance from the insulating material to the transition face along the first diameter portion is less than the diameter of the first diameter portion (column 5, lines 1-19).

Regarding claim 10, Cunningham et al. discloses wherein the distance from the insulating material to the transition face along the first diameter portion is approximately 0.9 millimeters (column 6, lines 59-61).

Regarding claim 11, Cunningham et al. discloses wherein the transition face extends at least 0.3 millimeters toward a center longitudinal axis of the electrode from the exposed surface of the electrode (column 6, lines 49-61).

Regarding claim 12, Cunningham et al. discloses the recessed region encircles the ablation electrode (view figure 2).

Regarding claim 13, Cunningham et al. discloses a largest diameter of the electrode is no larger than a diameter of the insulating material forming the first sidewall (view figure 3).

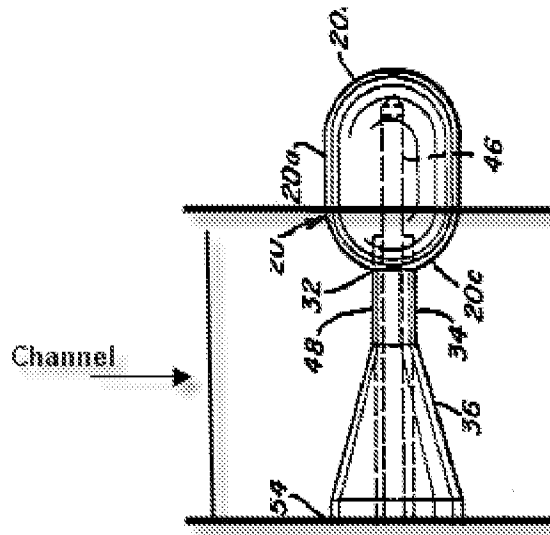
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Regarding claim 14, Cunningham et al. discloses the transition face is parallel to a distal end of the catheter shaft (view figures 2 and 3).

Regarding claim 16, Cunningham et al. discloses wherein the first diameter portion and the insulating material form an angle of more than 90 degrees (view figure 2).

Regarding claim 18, Cunningham et al. discloses wherein the ablation electrode is approximately four millimeters in length (column 6, lines 53-55).

Regarding claim 19, Cunningham et al. discloses shaft including an electrically insulating material((54); column 3, lines 15-19); and an ablation electrode forming a junction with the insulating material and having an exposed surface that forms a channel with the insulating material(view figures 2 and 3; view figure below); wherein a base of the channel is the exposed electrode surface of a first diameter portion of the electrode; a first sidewall of the channel is the insulating material; a second sidewall of the channel is the exposed electrode surface of a second diameter portion of the electrode; and a length of the second diameter portion of the electrode is greater than a diameter of the second diameter portion (view figures below; column 4 line 67-column 5 line 19).



Regarding claim 20, Cunningham et al. discloses the second sidewall forms an angle of less than 120 degrees with the channel base (view figures 2 and 3).

Regarding claim 21, Cunningham et al. discloses the channel allows blood to flow across the channel base and the second sidewall when the electrode is placed in a blood flow (view figures 2 and 3).

Regarding claim 23, Cunningham et al. discloses wherein the ablation electrode is a distal tip ablation electrode (column 9, lines 25-29).

Regarding claim 24, Cunningham et al. discloses wherein the ablation electrode is a ring ablation electrode (column 7, lines 11-15).

Regarding claim 26, Cunningham et al. discloses the distance from the first sidewall to the second sidewall along the base is more than 0.3 millimeters (column 5, lines 15-19; column 6, lines 49-61).

Regarding claim 27, Cunningham et al. discloses wherein the distance from the first sidewall to the second sidewall along the base is less than a diameter of the first diameter portion (column 5, lines 15-19; column 6, lines 49-61).

Regarding claim 28, Cunningham et al. discloses the second sidewall extends at least 0.3 millimeters toward a center longitudinal axis of the electrode from an outer surface of the electrode (column 6, lines 49-61).

Regarding claim 29, Cunningham et al. discloses the channel encircles the ablation electrode (view figure 2).

Regarding claim 30, Cunningham et al. discloses a largest diameter of the electrode is no larger than a diameter of the insulating material forming the first sidewall (view figures 2 and 3).

Regarding claim 31, Cunningham et al. discloses wherein the ablation electrode is approximately four millimeters in length (column 6, lines 53-55).

Regarding claim 32, Cunningham et al. discloses a catheter having an insulating sheath(54); and an ablation electrode non-moveably attached to the insulating sheath(20), forming a junction with the insulating sheath, and having an exposed surface that forms a channel with the insulating sheath; wherein a base of the channel is the exposed electrode surface; a first sidewall of the channel is the insulating sheath; a second sidewall of the channel is the exposed electrode surface; and a width of the base of channel is at least one-tenth of the size of the largest diameter of the electrode and less than the smallest diameter of the electrode((column 4 line 67-column 5, line 19). Cunningham discloses that the insulation is terminated one millimeter from

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the electrode (column 6, lines 59-61). The largest diameter is disclosed as 7 French which is 2.33mm. The smallest diameter is shown as smaller than 7 French. Therefore the base is **at least** one-tenth of the largest diameter and is less than the smallest diameter.

Regarding claim 33, Cunningham et al. discloses wherein the electrode (20) is a distal tip electrode (column 9, lines 25-29).

Regarding claim 34, Cunningham et al. discloses wherein the electrode (20) is a ring electrode (column 7, lines 11-15).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. **Claims 4 and 22** are rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham et al. (US 4,896,671) in view of He (US 2003/0028185 A1).

Regarding claim 4, Cunningham et al. discloses the claimed catheter but fails to disclose wherein the ablation electrode further comprises a plurality of recessed regions that allow blood to flow across exposed surfaces of the recessed regions when the electrode is placed in a blood flow.

However, He discloses the ablation electrode further comprises a plurality of recessed regions that allow blood to flow across exposed surfaces of the recessed regions when the electrode is placed in a blood flow (view figures 8A and 8B).

8. It would have been obvious to one having ordinary skill in the art at the time of invention to combine the catheter taught by Cunningham with the catheter having an ablation electrode further comprises a plurality of recessed regions that allow blood to flow across exposed surfaces of the recessed regions when the electrode is placed in a blood flow taught by He. Doing so would allow the surgery to be more efficient by allowing the tip to be cooled with the passing blood.

Regarding claim 22, Cunningham discloses the claimed catheter, but fails to disclose wherein the ablation electrode further comprises a plurality of channels that allow blood to flow across exposed surfaces of the channels when the electrode is placed in a blood flow.

However, He discloses the ablation electrode further comprises a plurality of channels that allow blood to flow across exposed surfaces of the channels when the electrode is placed in a blood flow (view figures 8A and 8B).

9. It would have been obvious to one having ordinary skill in the art at the time of invention to combine the catheter taught by Cunningham with the catheter having a

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plurality of channels taught by He. Doing so would allow the surgery to be more efficient by allowing the tip to be cooled with the passing blood.

10. **Claims 15, 17, and 25** are rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham et al (US 4,896,671) in view of Swanson et al (US 6,514,246 B1).

11. **Regarding claim 15**, Cunningham et al. discloses the claimed catheter, but fails to disclose wherein the first diameter portion and the insulating material form an angle of approximately 90 degrees.

However, Swanson et al. discloses the first diameter portion and the insulating material form an angle of approximately 90 degrees (view figure 12 b).

12. It would have been obvious to one having ordinary skill in the art at the time of invention to modify the catheter taught by Cunningham with the catheter taught by Swanson. Doing so would still allow the catheter to be used for ablation as well as giving a sharper angle between the insulation and the electrode in order to improve surgery time.

Regarding claim 17, Cunningham et al. discloses the claimed catheter, but fails to explicitly disclose wherein the first diameter portion and the insulating material form an angle less than 90 degrees.

However, Swanson et al discloses diameter portion and the insulating material form an angle less than 90 degrees (view figure 27 and 28).

13. It would have been obvious to one having ordinary skill in the art at the time of invention to modify the catheter taught by Cunningham with the catheter taught by

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Swanson. Doing so would still allow the catheter to be used for ablation as well as giving a smaller angle between the insulation and the electrode in order to improve surgery time.

Regarding claim 25, Cunningham et al. discloses the claimed catheter, but fails to explicitly disclose wherein the second sidewall forms an approximately 90 degree angle with the channel base.

However, Swanson et al. discloses second sidewall forms an approximately 90 degree angle with the channel base (view figure 12b).

14. It would have been obvious to one having ordinary skill in the art at the time of invention to modify the catheter taught by Cunningham with the catheter taught by Swanson. Doing so would still allow the catheter to be used for ablation as well as giving a sharper angle between the insulation and the electrode in order to improve surgery time.

15. **Claims 35, as far as it is definite, and 36** are rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham et al. (US 4,896,671).

Regarding claim 35, Cunningham does not explicitly disclose a method of manufacturing a catheter tip, comprising: providing a catheter shaft with an insulating sheath; providing an ablation electrode having a first diameter portion with an exposed surface and a second diameter portion with an exposed surface, the first and second diameter portions forming a transition face.

However, Cunningham does disclose a well known manufacture of catheter tips including a catheter shaft (12) with an insulating sheath(54), an ablation electrode

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having a first diameter portion with an exposed surface(20a) and a second diameter portion with an exposed surface(20c), and the first and second diameter portions forming a transition face (view figures 2 and 3).

16. It would have been obvious to one having ordinary skill in the art at the time of invention to manufacture the catheter tip in the claimed way. Doing so would allow the electrode to be manufactured because it has all of the claimed parts.

Regarding claim 36 Cunningham et al. does not explicitly disclose a method of manufacturing a catheter, wherein attaching the electrode to the shaft results in the base of channel being at least 0.9 millimeters wide from sidewall to sidewall.

However, Cunningham does disclose a well known method of manufacture of catheter tips including: the electrode (20) to the shaft (12) results in the base of channel being at least 0.9 millimeters wide from sidewall to sidewall (column 6, lines 59-61).

17. It would have been obvious to one having ordinary skill in the art at the time of invention to manufacture the catheter tip in the claimed way. Doing so would allow the electrode to be manufactured because it has all of the claimed parts.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. **Cosman (US 4,966,597); Imran (US 5,348,554); Levin (US 6,078,830).**

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMANDA SCOTT whose telephone number is (571)270-7103. The examiner can normally be reached on Monday thru Friday, 9:00 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrell McKinnon can be reached on (571)272-4797. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/AMANDA SCOTT/
Examiner, Art Unit 4185

/Edward K. Look/
Supervisory Patent Examiner, Art Unit 3745